

U.S. Serial No. 10/045,544
Group Art Unit: 3731

Docket No. ATA-333

Remarks

Upon entry of this Amendment, claims 1 through 57 are pending in the application. Claims 1-7, 10-15, 19-21, 23, 24, 26-36, 38, 39, 41-54, 56 and 57 are rejected. Claims 8, 9, 16-18, 22, 25, 37, 40 and 55 are indicated as having allowable subject matter, but are objected to as depending from rejected base claims. Claims 7-9 and 57 are amended herein. Reconsideration and allowance of all rejected claims are requested in view of the remarks below.

Claim Rejections – 35 U.S.C. §112

Claims 7-9 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claims 7-9 and 57 to more precisely claim aspects of the invention. In view of the amendments, Applicants submit that the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claim Rejections – 35 U.S.C. §102

Claims 1-7, 13-15, 19-21, 23, 24, 26-28, 30-32, 35, 36, 38, 39, 41-46, 48-51, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Buselmeier (3,826,257). Applicants traverse this rejection.

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Buselmeier involves a subcutaneous U-shaped shunt tube 15 of preshaped Silastic. Access tubes 16 are connected with the shunt tube 15 between the ends. A removable plug 13 is provided to entirely fill the full length of each of the access tubes 16 and is removable to obtain access to the blood in the shunt tube 15. Only the head or extraluminal protrusion 14 of the plug is normally visible on the access tube 16. See column 5, lines 11-23, the abstract and Figure 4 of Buselmeier. It is apparent from Buselmeier that insertion and removal of the plug 13 can only be done through the distal end of the access tube 16.

Conversely, various embodiments of the present invention provide a body fluid cartridge exchange platform device having a hollow tubular platform housing. As recited in claim 1, the hollow tubular platform housing has a first end with a first opening and a second end with a second opening, wherein the first opening and the second opening facilitate insertion of a tubular cartridge insert that sealably engages inside the platform housing. Claim 1 further recites that the first opening and the second opening facilitate bi-directional installation and bi-directional removal of the tubular cartridge insert.

Applicants' specification describes the term bi-directional. By way of example, page 19, lines 24-32, provides:

In accordance with one embodiment of the present invention, the body fluid cartridge exchange platform device includes a tubular housing with an interior sealing surface having two openings, one at each end. The existence of the two horizontally oriented tubular openings enables a patient, family member,

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or healthcare worker, to bi-directionally insert, exchange and or remove the tubular cartridge inserts. The tubular and generally oval shaped cartridge inserts can be constructed of one or more assembled elements or parts to form one leak-proof tubular cartridge unit, or formed as a multi-cartridge, leak-proof assembly unit. The cartridge insert can easily be inserted, displaced, and removed out through either open end of the cartridge platform housing....

Further examples of the term "bi-directional" can be found throughout the specification, such as at page 15, lines 23-25, page 22, lines 19-20, page 38, lines 7-14, page 43, lines 29-31, and page 54, line 31 to page 55, line 2.

In view of the above, Applicants submit that bi-directional installation and bi-directional removal involves an ability to install the cartridge insert in two directions and remove the cartridge insert in two directions. As Buselmeier provides only a single direction for insertion and a single, opposite direction for removal, Applicants submit that Buselmeier does not teach or suggest the all the limitations of claim 1. Claims 2-7 and 13-15 are patentable at least by way of their dependency from claim 1.

Claim 19 recites a cartridge being insertable and removable through the first and second openings of a housing. Buselmeier provides only a single opening at the distal end of the access tube 16 for insertion and removal. Even if the plug of Buselmeier were considered analogous to the cartridge of the present invention, Applicants submit that claim 19 is patentable over Buselmeier at least because Buselmeier does not recite a cartridge being insertable and removable through a first and second opening. Buselmeier

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provides only the distal end of the access tube 16 for insertion and removal of each of the plugs 13. Claims 20-21, 23-24, 26-28, 30-32, 35-36 and 38-39 are patentable at least by way of their dependency from claim 19.

Claim 24 recites a channel disposed within a cartridge, wherein the channel completes a flow path between a first passage and a second passage through first and second ports. Applicants submit that claim 24 is also patentable at least because Buselmeier does not anticipate such a channel.

Claim 41 recites an access device for providing access to internal organs. The device has a housing having a first opening at a first end and a cartridge suitable for sealingly engaging an interior of the housing. Applicants submit that Buselmeier does not anticipate claim 41 at least because the plug 13 of Buselmeier does not anticipate the cartridge of claim 41. In Buselmeier, the plug 13 must be removed to obtain access to the blood in the shunt tube 15, see the Abstract. Therefore, if the plug is in place, the device does not provide access to internal organs, as recited in claim 41. Consequently, Applicants submit that Buselmeier does not anticipate claim 41 at least because Buselmeier does not teach an access device for providing access to internal organs having a cartridge suitable for sealingly engaging an interior of the housing. Claims 42-46, 48-51 and 54 are patentable at least by way of their dependency from claim 41. Claim 43 is also patentable for the reasons described above in relation to claim 19.

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Claim Rejections – 35 U.S.C. §103

Claims 10, 33, 53, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier. Applicants traverse this rejection. In view of the discussion above, claim 10 is patentable at least by way of its dependency from claim 1. Claim 33 is patentable at least by way of its dependency from claim 19. Claim 53 is patentable at least by way of its dependency from claim 41.

Similar to claim 1, discussed above, claim 56 is patentable over Buselmeier at least because claim 56 recites that the first opening and the second opening facilitate bi-directional installation and bi-directional removal of the tubular cartridge insert.

Claims 11, 34, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier in view of Schulte (3,853,126). Applicants traverse this rejection.

Schulte does not overcome the deficiencies discussed above in relation to claim 1. Therefore, claim 11 is patentable at least by way of its dependency from claim 1. Similarly, Schulte does not overcome the deficiencies of Buselmeier relative to claims 19 or 41. Therefore, Applicants submit that claims 34 and 52 are patentable at least by way of their dependency from claim 19 and 41, respectively.

Claims 12, 29, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier in view of Santerre et al. (5,798,115). Applicants traverse this rejection.

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Santerre does not overcome the deficiencies discussed above in relation to claim

1. Therefore, claim 12 is patentable at least by way of its dependency from claim 1.

Similarly, Santerre does not overcome the deficiencies of Buselmeier relative to claims 19 or 41. Therefore, Applicants submit that claims 29 and 47 are patentable at least by way of their dependency from claim 19 and 41, respectively. Claim 29 is also patentable at least by way of its dependency from claim 24, discussed above.

Conclusion

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. Accordingly, allowance is requested. If there

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are any remaining issues or the Examiner believes that a telephone conversation with the Applicant's attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,

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